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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUN PHARMACEUTICAL INDUSTRIES LTD. and RANBAXY SIGNATURE, LLC, Plaintiffs, v. VISTAPHARM, INC., Defendant.	Honorable Civil Action No. **COMPLAINT**

Plaintiffs Sun Pharmaceutical Industries Ltd. and Ranbaxy Signature, LLC (collectively, "Plaintiffs"), for their Complaint against Defendant VistaPharm, Inc. ("VistaPharm"), hereby allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement of United States Patent No. 6,890,957 ("the '957 patent") arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.*, including Hatch-Waxman Act, 35 U.S.C. § 271(e)(2) and § 271(a). This action arises from VistaPharm's filing of Abbreviated New Drug Application No. 212677 (the "VistaPharm ANDA") with the United States Food and Drug Administration ("FDA") seeking

approval, prior to the expiration of the ’957 patent, to manufacture, market, and sell a generic copy of RIOMET® (metformin hydrochloride) oral solution.

PARTIES

2. Plaintiff Sun Pharmaceutical Industries Ltd. (“Sun”) is an entity organized and existing under the laws of India having a principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra 400063, India.

3. Plaintiff Ranbaxy Signature, LLC (“Ranbaxy Signature”) is an entity organized and existing under the laws of Delaware having a principal place of business at 600 College Road East, Suite 2100, Princeton, NJ 08540.

4. Upon information and belief, Defendant VistaPharm, Inc. is an entity organized and existing under the laws of Alabama, with its principal place of business at 630 Central Avenue, New Providence, NJ 07974.

5. Upon information and belief, VistaPharm participated in the research and development, and the preparation and filing, of the VistaPharm ANDA for metformin hydrochloride oral solution (the “VistaPharm ANDA Product”), continues to participate in seeking FDA approval of that application, and intends to participate in the commercial manufacture, marketing, offer for sale, and sale of the VistaPharm ANDA Product throughout the United States, including in the State of New Jersey, in the event the FDA approves the VistaPharm ANDA.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America, United States Code, Title 35 § 1, *et seq.*, including §§ 271(e)(2) and 271(a). This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over VistaPharm because its principal place of business is located in New Jersey. This Court also has personal jurisdiction over VistaPharm by

virtue of, *inter alia*, the fact that VistaPharm has engaged in purposeful systematic and continuous contacts with the State of New Jersey. This Court has personal jurisdiction over VistaPharm for the additional reasons set forth below and for other reasons that will be presented to the Court if jurisdiction is challenged.

8. This Court has personal jurisdiction over VistaPharm because, upon information and belief, VistaPharm regularly does business in New Jersey and has engaged in a persistent course of conduct within New Jersey by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including New Jersey, and/or by directly selling pharmaceutical products in New Jersey.

9. This Court has personal jurisdiction over VistaPharm by virtue of, *inter alia*, the fact that VistaPharm distributes drug products for sale throughout the United States, including in this judicial district.

10. This Court has personal jurisdiction over VistaPharm because, on information and belief, VistaPharm has engaged in conduct (including having committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement) that reliably predicts New Jersey activities by VistaPharm and that has led to foreseeable harm and injury to Plaintiffs in New Jersey. On information and belief, by preparing and/or filing ANDA No. 212677 seeking approval to market a generic copy of Plaintiffs' branded product, RIOMET®, VistaPharm has taken the significant step of applying to the FDA for approval to engage in future activities that will be purposefully directed to New Jersey. Upon information and belief, VistaPharm has distribution channels and plans to market and sell its generic product throughout the United States, including in this judicial district, before the expiration of the '957 patent.

11. This Court has personal jurisdiction over VistaPharm by virtue of the fact that VistaPharm has availed itself of the rights and benefits of New Jersey law, and has engaged in systematic, continuous, constant, and pervasive contacts with the State of New Jersey.

12. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENT-IN-SUIT

13. On May 10, 2005, the ’957 patent, titled “Liquid Formulation of Metformin,” was duly and lawfully issued by the United States Patent and Trademark Office (“USPTO”). Ranbaxy Signature is the sole owner of the ’957 patent. Sun has exclusive marketing, promotion, distribution, and sales rights to products covered by the ’957 patent on a worldwide basis. A copy of the ’957 patent is attached hereto as Exhibit A.

RIOMET®

14. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ’957 patent is listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with FDA-approved New Drug Application (“NDA”) No. 021591, submitted by Sun, as covering RIOMET® (metformin hydrochloride) oral solution 500 mg/5 mL.

THE VISTAPHARM ANDA

15. On or about January 18, 2019, Plaintiffs received a letter from VistaPharm, dated January 17, 2019, regarding “Notification Pursuant to Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act for U.S. Patent No. 6,890,957 (NDA No. N021591)” (“VistaPharm’s Purported Notice Letter”). VistaPharm’s Purported Notice Letter states that VistaPharm submitted an ANDA to the FDA under 21 U.S.C. 355(j), seeking FDA approval to manufacture, offer to sell, and sell a generic copy of RIOMET®.

16. The VistaPharm ANDA includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355 (j)(2)(B)(iv) ("VistaPharm's Paragraph IV Letter"). Attached to VistaPharm's Paragraph IV Letter was a statement of the factual and legal bases for VistaPharm's opinion that "all claims of [the '957 patent] are invalid, unenforceable or not infringed, either literally or under the doctrine of equivalents, by the manufacture, use or sale of VistaPharm's proposed Oral Solution." VistaPharm's Paragraph IV Letter did not identify any factual or legal basis as to why the '957 patent is invalid beyond its assertion that the claims of the '957 are not infringed.

17. The VistaPharm ANDA states that it was filed by VistaPharm.

18. Upon information and belief, the VistaPharm ANDA was submitted to the FDA for approval to market a generic copy of RIOMET® prior to the expiration of the '957 patent.

19. Upon information and belief, the VistaPharm ANDA refers to and relies upon the RIOMET® NDA and contains data that, according to VistaPharm, demonstrate the required bioavailability and/or bioequivalence of the VistaPharm ANDA Product and RIOMET®.

20. Upon information and belief, upon FDA approval of the VistaPharm ANDA, VistaPharm will market and distribute the VistaPharm ANDA Product to resellers, pharmacies, hospitals and other clinics, health care professionals, and end users of the VistaPharm ANDA Product throughout the United States, including in this judicial district.

21. Plaintiffs filed this Complaint and commenced action within 45 days of the date of receipt of VistaPharm's Purported Notice Letter dated January 17, 2019.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 6,890,957

22. Plaintiffs re-allege and incorporate by reference the allegations of paragraphs 1-21 of this Complaint as if fully set forth herein.

23. The '957 patent is valid and enforceable, and Plaintiffs have complied with all applicable regulations and laws.

24. VistaPharm infringes the ’957 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the VistaPharm ANDA, which seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the VistaPharm ANDA Product prior to the expiration of the ’957 patent.

25. VistaPharm’s commercial manufacture, use, offer to sell, or sale of the VistaPharm ANDA Product within the United States, or importation of the VistaPharm ANDA Product into the United States during the term of the ’957 patent also would infringe the ’957 patent under 35 U.S.C. § 271(a), (b), and/or (c), either literally or under the doctrine of equivalents.

26. VistaPharm’s commercial manufacture, use, offer to sell, or sale of the VistaPharm ANDA Product within the United States, or importation of the VistaPharm ANDA Product into the United States during the term of the ’957 patent would infringe at least Claim 1 of the ’957 patent because, upon information and belief, the VistaPharm ANDA Product contains, either literally or under the doctrine of equivalents, a liquid pharmaceutical composition for oral administration which comprises a therapeutically effective amount of metformin or its pharmaceutically acceptable salt; a sweetener that does not increase the blood glucose level of a subject after ingestion thereof; a polyhydroxy alcohol present in an amount of about 15 to about 55% by weight; a mineral acid and bicarbonate salt both present in sufficient amounts to maintain the pH of the composition in the range of about 4.0 to about 9.0; and a pharmaceutically acceptable liquid carrier.

27. Upon information and belief, VistaPharm had actual and constructive knowledge of the ’957 patent prior to filing the VistaPharm ANDA, and was aware that the filing of the VistaPharm ANDA with the request for FDA approval before the expiration of the ’957 patent would constitute an act of infringement of the ’957 patent.

28. The commercial manufacture, importation, use, sale, or offer for sale of the VistaPharm ANDA Product in violation of Plaintiffs' patent rights will cause harm to VistaPharm for which damages are inadequate.

29. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for the VistaPharm ANDA to be a date that is not earlier than the expiration date of the '957 patent.

30. Unless and until VistaPharm is enjoined from infringing the '957 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against VistaPharm, and respectfully request the following relief:

A. A judgment that VistaPharm has infringed at least one valid claim of the '957 patent under 35 U.S.C. § 271(e)(2) by submitting the VistaPharm ANDA to the FDA;

B. A declaratory judgment that, under one or more of 35 U.S.C. §§ 271(a), (b), and/or (c), VistaPharm's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of the VistaPharm ANDA Product would constitute infringement of one or more claims of the '957 patent;

C. A permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B), enjoining VistaPharm, its affiliates and subsidiaries, and all persons and entities acting in concert with VistaPharm from commercially manufacturing, using, offering for sale, selling, or importing the VistaPharm ANDA Product into the United States, until the expiration of the '957 patent;

D. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of ANDA No. 212677 shall be no earlier than the expiration date of the '957 patent, or the expiration date of any exclusivity to which Plaintiffs are or become entitled;

E. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if VistaPharm engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the VistaPharm ANDA Product, or any product that infringes the '957 patent, prior to the expiration of the '957 patent.

F. A judgment that this is an exceptional case under 35 U.S.C. § 285, and awarding Plaintiffs their reasonable attorneys' fees;

G. An award to Plaintiffs of their costs and expenses in this action; and

H. Such other and further relief as the Court may deem just and proper.

WINSTON & STRAWN LLP
Attorneys for Plaintiffs, Sun Pharmaceutical Industries Ltd. and Ranbaxy Signature, LLC

Dated: March 1, 2019

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CERTIFICATION PURSUANT TO L. CIV.R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that to my knowledge the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

s/James S. Richter

Dated: March 1, 2019

CERTIFICATION PURSUANT TO L. CIV.R. 201.1

Pursuant to Local Civil Rule 201.1(d)(3), I hereby certify that because this action seeks injunctive and declaratory relief, the value of which cannot be quantified, and, therefore, the relief sought exceeds the sum of $150,000, exclusive of interest and costs and any claim for punitive damages.

s/James S. Richter

Dated: March 1, 2019